

REMARKS

Claims 1-3, 5-7, 20, 21, and 34-36 are pending in the application. Claims 1, 2, 5, 6, 14-19, 20 and 21 are currently amended. Claims 8, 8-13, 22-33 and 37-52 are cancelled.

Claim Rejections – 35 U.S.C. 112 First Paragraph

Claim 1, 14-21, 34-36, 47 and 50 stand rejected under 35 U.S.C. 112 First Paragraph. The amendment to recite "zinc" renders this rejection moot.

Claim Rejections – 35 U.S.C. 112 Second Paragraph

Claims 2, 20, and 21 stand rejected under 35 U.S.C. 112 second Paragraph as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention for use of the word includes. "Includes" should be interpreted according to its plain meaning which means that at least the particular species of antioxidant including nordihydroguaiaretic acid or ascorbic acid are present. "Includes" is not a vague term and is present in the claims of most issued patents. In case the examiner has any remaining doubt about what "includes means, claims 20 and 21 have been if anything broadened to recite "at least." The issue of "includes" in claim 2 is moot do to another amendment to the claim.

Claims 2 and 42 stand rejected for recitation of "about." This term should be construed as it would be interpreted by a person of ordinary skill in the art. Generally, it means closely approximating the ratio of 1:2. This does not present a problem of understanding to the level of ordinary skill, but merely recognizes that some measurements may be inexact.

The objection to claim 35 is overcome by deleting the word "an."

Withdrawal of the rejection under 35 U.S.C. 112 second Paragraph is respectfully requested.

Claim Rejections – 35 U.S.C. 103

Claims 1-6, 14-15, 19-21, 39, 41-43, 45-46 and 50 stand rejected over EP 506,207 in view of applicant's disclosure on page 2. The examiner asserts that 8-

hydroxyquinoline is a known antifungal agent and chelating agent, so a person of ordinary skill would have been motivated to combine this with zinc chloride as taught in the '207 patent.

One fallacy in this rejection is that EP '207 does not teach the use of 8-hydroxyquinoline, rather, it teaches only the use of halogenated and sulfated derivatives of 8-hydroxyquinoline. The passage from the specification that is relied upon by the examiner is actually misquoted by the examiner, and so also misapplied. The passage says that 8-hydroxyquinoline in combination with dehydroascorbic acid or sorbic acid is used as a fungistat. This differs from the use of halogenated derivatives of 8-hydroxyquinoline, which alone may be used as fungistats—typically in dilute quantities where such concentrations are specified. EP '207 also teaches the use of sulfated forms of 8-hydroxyquinoline as antimycotics, but again this is not a combination fungistat. The point is that 8-hydroxyquinoline is excluded from this list due to relatively poor efficacy as a fungistat.

We have previously submitted with our response dated October 26, 2004, a Declaration of Carl Hansen showing that the use of 8-hydroxyquinoline in the claimed composition was effective against precancerous lesions, whereas the sulfated form had a total lack of efficacy. This should be an important factor in the determination of nonobviousness, since it shows that the list of fungicides in EP '207 do not all behave in an equivalent manner as anticancer drugs. This is even true as to the 8-hydroxyquinoline derivatives. Since the art is unpredictable as to what will work and efficacy as an antimycotic is not a predictor of success as a cancer drug, this case is analogous to *In re Papesch*, 315 F.2d 381 (CCPA 1963) where the unexpected effects of an alleged chemical "homologue" sustained a decision for nonobviousness:

To those skilled in the chemical art, one homologue is not such an 'advance' over an adjacent member of the series as requires invention, unless the beneficial properties realized in the new homologue lie clearly outside of the expectations which knowledge of his science would inform the trained chemist should be inherent in the product.

Id. at 388.

The halogenated forms of 8-hydroxyquinoline are now known themselves to be carcinogenic.

Under such circumstances, the Examiner has not made a *prima facie* showing of obviousness by predicated a highly uncertain and speculative showing of anticancer utility upon a possible combination that may be selected from among a broad list of antimycotics that: (A) were not show to have been actually used and (B) when used have been show to be either ineffective against cancer or themselves to be carcinogenic. To the extent the Examiner believes a *prima facie* showing has been made, it has also been rebutted by the comparative evidence showing that the sulfated forms of 8-hydroxyquinoline are not equivalent to 8-hydroxyquinoline itself. Under these circumstances a patent must be allowed to issue.

The amended claims are patentable for the above reasons. This response is being filed with fee for the Petition for Extension of Time. Applicant believes that no additional fees are due at this time. However, if any additional fees are due, the Commissioner is authorized to charge them to deposit account No. 12-0600.

Respectfully submitted,

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